DEC 21 2001

Chapter 1 – Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K013900.

1. Submitter name, address, contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(716) 453-4041

Contact Person: Marlene A. Shulman

Date 510(k) prepared: November 21, 2001

2. Device Name

Trade or Proprietary Name: VITROS Immunodiagnostic Products Vitamin B12 Range Verifiers
Common Name: Range Verifiers
Classification Name: VITROS Range verifiers for use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of immunoassays which include Vitamin B12.

3. Predicate Device

The VITROS Immunodiagnostic Products Vitamin B12 Range Verifiers are substantially equivalent to VITROS Immunodiagnostic Products Vitamin B12 Range Verifiers (K990026).

4. Device Description

The VITROS Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum, plasma and urine. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The VITROS ECi Immunodiagnostic Products (in this case VITROS Immunodiagnostic Products Range Verifiers, which are used along with VITROS Immunodiagnostic Products Reagent Pack and VITROS Immunodiagnostic Products Calibrators by the VITROS ECi Immunodiagnostic System to verify the performance of the VITROS assay).

2. The VITROS ECi Immunodiagnostic System - instrumentation, which provides automated use of the immunoassay kits. The VITROS ECi System was cleared for market by a separate 510(k) pre-market notification (K962919).

3. Common reagents used by the VITROS ECi System in each assay. The VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent were cleared as part of the VITROS Immunodiagnostic Products Total T3 510(k) pre-market notification (K964310).

The VITROS ECi System and common reagents are dedicated specifically only for use with the VITROS Immunodiagnostic Products range of immunoassay products.

5. Device Intended Use

For *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of Vitamin B12.

6. Comparison to Predicate Device

The VITROS Immunodiagnostic Products Range Verifiers are substantially equivalent to VITROS Vitamin B12 Range Verifiers (predicate device), which was approved by FDA (K990026) for IVD use.

Table 1 lists the similarities and differences of the device characteristics between the VITROS Vitamin B12 Range Verifiers with the predicate device, previously-cleared VITROS Vitamin B12 Range Verifiers.

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Table 1 List of the assay characteristics

Characteristics	New Device	Predicate Device
Intended use	For use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of Vitamin B12.	For use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of Vitamin B12.
Matrix of Range Verifiers	Buffered matrix containing liquid human serum albumin	Buffered matrix containing liquid human serum albumin
Range Verifier levels	Low: Target Concentration: <90 pg/mL High Level: Target Concentration: 925 pg/mL	Low: Target Concentration: <50 pg/mL High Level: Target Concentration: 1900 pg/mL

7. Conclusions

The data presented in the pre-market notification demonstrate that the VITROS Vitamin B12 Range Verifiers are substantially equivalent to the predicate device, for which there is FDA clearance.

Equivalence was demonstrated by comparing the physical properties and intended uses of these devices with commercially available reagents.

The data presented in the premarket notification provide a reasonable assurance that the VITROS Vitamin B12 Range Verifiers are safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 2001

Ms. Marlene A. Shulman
Regulatory Affairs Associate
Ortho-Clinical Diagnostics Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k013900
Trade/Device Name: VITROS Immunodiagnostic Products Vitamin B12 Range Verifiers
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: I, reserved
Product Code: JJX
Dated: November 21, 2001
Received: November 23, 2001

Dear Ms. Shulman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K013900

Device Name: VITROS Immunodiagnostic Products Vitamin B12 Range Verifiers

Indications for Use: For *in vitro* use in verifying the calibration range of the VITROS Immunodiagnostic System when used for the measurement of Vitamin B12.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013900

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)